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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/574,946	SHEWMAKER ET AL.
	Examiner	Art Unit
	David T. Fox	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 July 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29,81-133 and 136-138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-29,81-133 and 136-138 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

The Assignee's offer of 21 December 2000 to surrender the original patent, as reiterated on page 16 of the amendment of 25 November 2002, is acknowledged.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed.

See 37 CFR 1.178.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,753,475 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

The amendments of 09 July 2004 have overcome the claim objections regarding minor errors, as set forth on page 2 of the Office action of 11 March 2004, and the obviousness-type double patenting rejection of claim 124 over U.S. Patent Nos. 5,750,385 and 4,943,674.

Claims 1-29, 81-133 and 136-138 are pending and have been examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that the reissue declaration of 12 December 2003 lists three errors on which the instant reissue application is purportedly based: "omission of appropriate method and composition claims", "failure to claim priority to co-pending application serial no. 07/988,158", and "failure of the USPTO to properly acknowledge the priority claimed to co-pending applications...". Of these three errors, only the second, namely the failure of Applicant to claim priority to a copending application, rises to the level of a correctable error on which a reissue application may be based. See MPEP 1402, fifth paragraph, item D; and 35 USC 251.

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The amendment of 09 July 2004 was not accompanied by a supplemental reissue declaration, as required by 37 CFR 1.175(b)(1)(i).

Claims 1-29, 81-133 and 136-138 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-29, 81-133 and 136-138 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR

1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application, as stated on pages 3-7 in the Office action of 27 September 2001 for claims 19-44 and 62-130.

Applicant's arguments filed in the response of 09 July 2004 on pages 5-6 have been fully considered but they are not persuasive. Applicant urges that the recapture rejection is improper, since the claims of the parent application on which the Examiner bases his arguments are not in fact drawn to the same or narrower subject matter than

the claims of the instant application. Specifically, Applicant urges that claims 107-108 of the parent application were not drawn to the same subject matter as the instant claims, but in fact were broader than the instant claims, as permitted by *In re Clement* cited previously. Applicant urges that the instant claims are drawn to the use of a transcriptional initiation region (or promoter) *specifically or preferentially* regulated in embryonic seed tissue (see claims 81 and 108 of the amendment of 09 July 2004), while claims 107-108 of the parent application are merely drawn to gene transcription “*during seed embryogenesis*” [emphasis mine]. Applicant further urges that claim 133 of the instant application was not subjected to the same art rejections as those applied to claim 101 in the parent application, thus refuting the Examiner’s position that recapture exists for this subject matter.

The Examiner maintains that claims 107-108 of the parent application were dependent claims, and must be interpreted in light of the limitations of the claims on which they depend. Claims 107 and 108 in the parent application depend upon either claim 22 or claim 70 (see page 9 of the amendment filed 23 October 1995 in parent application Serial No. 08/105,852). Claim 70 of the parent application recites a method of “altering the phenotype of seed...tissue as *distinct from other plant tissue* ...comprising growing a plant...containing a DNA construct...comprising a transcriptional initiation region from a gene...regulated in...seed tissue...whereby said DNA sequence of interest is transcribed under transcriptional control of said transcriptional initiation region” (see pages 7-8 of the amendment of 23 October 1995 in

the '852 application, emphasis added). Thus, claim 70 is drawn to the use of a seed-specific transcriptional initiation region.

Claim 107 of the parent application further limits claim 70 by reciting that the seed-specific transcription initiation occurs in seed tissue during seed embryogenesis. This is equivalent to the instantly claimed subject matter, namely the use of a transcriptional initiation region which is preferentially or specifically regulated in embryonic seed tissue. Furthermore, claim 108 of the parent application recites the specific timeframe of gene transcription of "about day 7 to day 40 postanthesis." This narrow recitation is nowhere present in the claims of the instant reissue, and is eminently germane to the art rejection. Thus, the reissue claims are in fact BROADER than those in the parent application, which broadening is prohibited by *In re Clement* cited previously and excerpted below.

Moreover, claims 22, 70, 107 and 108 in the parent application were rejected under 35 USC 103 in the Office action of 29 August 1996 (see pages 4-6 of that action), and were subsequently cancelled by the amendment of 02 January 1997, resulting in allowance of the remaining claims, all of which were drawn to fruit-specific promoters.

See *In re Clement*, 45 USPQ2d 1161, (Fed. Cir. 1997) at page 1165:

(3) if the reissue claim is broader in some aspects, but narrower in others, then (a) if the reissue claim is as broad as or broader *in an aspect germane to a prior art rejection* [emphasis added], but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim.

Regarding claim 101 of the parent application, the Examiner maintains that the claim was limited to an isolated plant cell (see page 6 of the amendment of 11 April 1995 in the '852 application), while instant claim 133 is drawn to a whole transformed

plant. Both claims are of similar scope regarding the promoter or transcriptional initiation region used to transform the plant cell or plant. However, Rogers et al applied to claim 101 under 35 USC 102(e) in the parent could not be applied to instant claim 133, since Rogers et al do not teach or claim whole transformed plants. Nonetheless, Rogers et al do teach the promoter recited in parent claim 101 and instant claim 133. Thus, the failure of the Examiner to apply Rogers et al to instant claim 133 was not an admission that the claim was drawn to different subject matter than that claimed in the parent application, regarding the subject of the instant reissue application, namely the use of a particular transcriptional initiation region. Thus, recapture of subject matter of the same scope germane to the inventive concept, namely the particular transcriptional initiation region, indeed occurs in the instant reissue application.

Regarding the failure of the Examiner to apply to instant claim 133 a rejection under 35 USC 103 over the same combination of art including Rogers et al, as was done in the parent application for claim 101, the Examiner maintains that such an omission is not probative of error in the Examiner's position. The choice of which art to apply in a prior art rejection is a matter of Examiner discretion, and the use of different art in a subsequently filed reissue application merely indicates that the Examiner chose art which more concisely supported his position. The fact remains that claim 101 in the '852 application was subjected to art rejections under both 35 USC 102 and 103 in the Office action of 21 June 1995, and was cancelled by Applicant in the amendment of 23 October 1995. That amendment also presented claims broadly drawn to any seed-specific promoter from any gene from any plant source, and methods of its use, as

stated above; which claims were encompassed by the subject matter of claim 101, and which claims were rejected under 35 USC 103 in the Office action of 29 August 1996, as stated above. In response to this art rejection, all claims not drawn to fruit-specific promoters were cancelled by the subsequent amendment.

Accordingly, claim 133 of the instant application, corresponding to the subject matter of parent claim 101 and other claims of the '852 application, constitutes an improper attempt to recapture the subject matter of the cancelled claims.

The effective filing date for claims 19-29, 81-130, 133 and 136-138, insofar as they are drawn to seed-specific promoters and their use, is 31 July 1986, the filing date of parent application Serial No. 06/891,529 which was the earliest parent to teach such a promoter, as stated on page 6 of the Office action of 11 March 2004.

Claims 19-29, 81-130, 133 and 136-138 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,420,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a seed-specific promoter and plant cells containing them, as claimed in the patent; to obtain the DNA constructs containing a seed-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on page 7 in the Office action of 11 March 2004.

Claims 97-100, 113-123, 125-128 and 131-133 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 1-8 of U.S. Patent No. 5,750,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain plant cells containing them, as claimed in the patent; to obtain the DNA constructs containing a chloroplast-containing-tissue-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on page 7 in the Office action of 11 March 2004 for claims 97-100, 113-128 and 131-133.

Claims 1-18, 97-100, 113-123, 125-128 and 133 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,943,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the patent; to obtain the DNA constructs containing a fruit-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as claimed in the instant application; as stated on pages 7-8 in the Office action of 11 March 2004 for claims 1-18, 97-100, 113-128 and 133.

Claims 19-29, 81-130, 133 and 136-138 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-47 and 50-54 of copending Application No. 09/782,130. Although the

conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the methods of obtaining seed-specific transcription or phenotypic alteration by plant transformation with seed-specific promoters including seed embryogenesis-specific promoters, as claimed in the copending application; to obtain the instantly claimed DNA constructs containing an embryonic seed-specific promoter and methods for their use to obtain transformed plant cells and plants containing them, as stated on page 8 of the Office action of 11 March 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's intent on page 6 of the amendment of 09 July 2004 to file Terminal Disclaimers is noted. The double patenting rejections will be maintained until receipt of properly executed Terminal Disclaimers.

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the use of *Brassica*-derived seed-specific promoters for seed-specific gene expression, transcription, or phenotypic alteration; or for light-inducible/chloroplast-containing-tissue-specific or fruit-specific promoters and methods for their use; does not reasonably provide enablement for claims broadly drawn to the use of any promoter or any regulatory sequence from any plant source to effect seed-specific gene expression, transcription or phenotypic alteration; or any promoter which would effect any type of plant developmental stage-specific expression. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 11-13 in the Office action of 27 September 2001 for claims 19-29 and 62-130.

Applicant's arguments filed on pages 6-7 of the response of 09 July 2004 have been fully considered but they are not persuasive.

Applicant urges that the enablement rejection is improper, given the lack of a requirement that every species encompassed by the claims be disclosed, the disclosure in the specification of various seed-specific promoters from various plant species, and the disclosure in the specification of how to isolate other seed-specific promoters.

Applicant also cites *In re Hogan* and *Plant Genetic Systems, N.V. v. Dekalb Genetics Corp.* to support her position.

The Examiner is not requiring that Applicant disclose every species encompassed by the claims. In fact, the Examiner has indicated that a broad genus of species, namely any seed-specific promoter from the plant genus *Brassica*, would be enabled by the limited disclosure of only three seed-specific promoters from three particular seed-specific *Brassica* genes. However, the claims encompass the much broader genus of any seed-specific promoter from any plant species from a multitude of unrelated taxonomic divisions.

Furthermore, claim 133 encompasses the much broader genus of *any* promoter preferentially active in *any* tissue, including tuber, trunk, branch, root, flower, stem, thorn, vascular element, bulb, or tendril. No representative species of this genus has been disclosed.

Regarding *Hogan*, the Examiner maintains that different fact patterns were involved. In *Hogan*, the CCPA overturned the Examiner's reliance upon material, published after the effective filing date of the patent application, to support his position that the claims were not enabled throughout their broad scope. The Court decided that it was improper for the Examiner to interpret the claims to encompass embodiments that were not envisioned at the time of filing the patent application. See 194 USPQ 527 at page 528, Headnotes 6 and 8. In the instant situation, Applicant's own disclosure clearly recites Applicant's attempt to encompass all seed-specific promoters from all genes from all plant species (see, e.g., column 8 of U.S. Patent 5,753,475, lines 3-9). Furthermore, the instant Examiner relied upon the state of the art at the time of filing the parent application to support his position. Thus, the teachings of *Hogan* do not pertain to the Examiner's rejection.

Regarding *Plant Genetic Systems v. Dekalb*, the Examiner maintains that the portion of that decision cited by Applicant on page 7 of the response of 09 July 2004 supports the Examiner's position. That excerpt requires that the patent "discloses how to make and use" "what was specifically desired but difficult to obtain at the time the application was filed". The portions of the '475 patent specification cited by Applicant on page 7 of the response of 09 July 2004 fail to "disclose how to make and use" what is instantly claimed. Column 8 of the '475 patent, lines 10-18 merely recite the desired time frames of expression of putative seed embryo genes from which promoters are desired to be isolated. No actual genes or transcription initiation regions are in fact disclosed. Column 30, line 63 to column 31, line 14 merely suggest other *Brassica*

genes from which transcription initiation regions may be isolated. This portion of the patent specification supports the Examiner's position that claims limited to *Brassica* transcriptional initiation regions are enabled, but does not teach "the identification of promoter regions" from any gene of any plant species, as asserted by Applicant.

Claims 19-29, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 13-14 of the Office action of 27 September 2001 for claims 19-29 and 62-130.

Applicant's arguments on pages 7-8 of the response of 09 July 2004 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the disclosure in the specification of various seed-specific promoters from various plant species and the disclosure in the specification of how to isolate other seed-specific promoters. Applicant also urges that *Enzo Biochem, Inc. v. Gen-Probe, Inc.* and *Amgen Inc. v. Hoescht Marion Roussel, Inc.* interpret *Eli Lilly* in a way that refutes the Examiner's reliance upon *Lilly*.

Regarding the cited portions of the patent specification, the Examiner maintains that these cited portions fail to teach what Applicant asserts they teach, as stated above. Furthermore, the Examiner maintains that the newly cited case law does not refute *Lilly* or the Examiner's reliance thereon.

Amgen Inc. v. Hoescht Marion Roussel excerpted on page 8 of the response of 09 July 2004 reiterates the Examiner's position that the written description requirement "may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure" [emphasis added].

The Examiner maintains that neither the specification nor the prior art provide any guidance regarding the identification of any structural features, i.e. conserved DNA sequences, common to all seed-specific promoters, as required by MPEP 2163, *Lilly*, and the Written Description Guidelines, all cited previously. Thus, inadequate written description of the broadly claimed genus, which encompasses all seed-specific promoters from all unrelated plant genera and species, has been provided by Applicant's disclosure of the isolation of three seed-specific promoters from *Brassica* genes. Similarly, no structural features have been disclosed which are common to all promoters which preferentially express at any "specific stage of plant growth" in any tissue or organ, as claimed in claim 133. See also *Bayer v. Housey* cited in the Office action of 11 March 2004.

Regarding *Enzo*, the Examiner maintains that *Enzo* supports his position. In *Enzo*, the Appellant deposited three nucleic acid probes from a single bacterium, *Neisseria gonorrhoeae*, and claimed any mutations thereof of any sequence, which mutations were not deposited (see pages 2-5 of the Federal Court decision, including excerpted claims 1 and 4). The Court reiterated the need for a correlation between structure, i.e. conserved nucleic acid sequence, and function, i.e. activity of the nucleic acid sequence, as set forth in *Lilly* (see pages 9 and 14-15 of the Decision). The Court

also reiterated the position set forth in *Lilly* that the disclosure of a nucleic acid sequence from one organism did not provide an adequate written description of a nucleotide sequence from another organism (see page 8 of the Decision). The Court then remanded the case to the District Court to determine if the deposit of three *Neisseria gonorrhoeae* nucleic acid sequences was sufficient to adequately describe claims broadly drawn to any sequence variant thereof (see page 13 of the Decision). Such a remand demonstrates that the Court did not yet recognize Appellant to have been in possession of the claimed invention, and did not believe that a person of ordinary skill would have understood this to be the case.

Furthermore, the claims in *Enzo* were limited to nucleic acid sequences from a single bacterial genus, unlike the instant application which does not recite a particular plant genus as source of the promoter. Thus, it is even less likely that the Court in *Enzo* would rule that the instant claims are supported by an adequate written description.

In the instant case, Applicants are broadly claiming any and all seed-specific promoters from any and all plant genera and species. Applicants have not provided any declaration or other evidence that they were in fact in possession of seed-specific promoters from any plant genus other than *Brassica* at the time of filing.

Claims 22, 24-27, 97-99, 101-102, 105, 107-109, 113-115, 117-118, 121, 123-125, 133 and 137 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al (U.S. Patent 5,504,200 effectively filed 15 April 1983), as stated on pages 13-15 of the Office action of 11 March 2004.

Applicant's arguments on page 9 of the response filed 09 July 2004 have been fully considered but they are not persuasive. Applicant urges that the Examiner indicated, in an Office action mailed 15 July 2003 in related application Serial No. 09/782,130, that Hall et al do not teach a phaseolin promoter operably linked to "a heterologous gene". Thus, the Examiner's earlier position in the related application contradicts the Examiner's later position in the instant application.

The Examiner maintains that Hall et al do indeed teach the phaseolin promoter operably linked to phaseolin cDNA, which intron-less cDNA is "other than the native coding sequence" of said gene, as instantly claimed, and as stated on page 14 of the Office action of 11 March 2004. Furthermore, the Examiner's position in an earlier-mailed Office action in a related application does not prevent his position from evolving over time, as indicated in the later-mailed Office action in the instant application.

Claims 19-27, 81-130, 133 and 136-138 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al., as stated on pages 19-21 of the Office action of 27 September 2001 for claims 19-27 and 62-130.

Applicant's arguments filed on pages 9-10 of the response of 09 July 2004 have been fully considered but they are not persuasive.

Applicant urges that the art rejections involving Sengupta-Gopalan et al are improper, since the enablement rejection has been overcome. The Examiner maintains that the enablement rejection has not been overcome, as discussed above. Furthermore, the enablement rejection applied to the instant application has no bearing

on the assignment of effective filing date based upon the sufficiency of the disclosure of various parent applications.

Regarding the sufficiency of disclosure of the earliest-filed parent application, the Examiner reiterates that the mere recitation in the earliest-filed parent application of a *light-inducible* promoter does not provide any enablement for isolated *seed-specific* promoters or methods of their use for plant transformation. The parent application does not demonstrate the identification or isolation of any seed-specific gene or its promoter, or plant transformation therewith. Thus, the instantly claimed subject matter was not adequately disclosed under 35 USC 112, first paragraph, in the earliest-filed parent application, so that Applicant is not entitled to the benefit of the earlier filing date. Accordingly, the teachings of Sengupta-Gopalan et al are available as prior art.

Applicant further urges that the Examiner's position regarding Hall et al in a related application contradicts his position in the instant application. This argument has been refuted above.

Applicant further urges that Sengupta-Gopalan et al does not provide the motivation to combine their teachings with those of Hall et al, and would not lead the ordinarily skilled artisan to expect successful expression of a heterologous gene under the control of a seed-specific promoter such as the phaseolin promoter. The Examiner maintains that the demonstration by Sengupta-Gopalan et al that the bean-derived phaseolin promoter functioned in a seed-specific way in a heterologous plant species, namely tobacco, did indeed provide a reasonable expectation of success that the

promoter would function to express heterologous coding sequences in a seed-specific manner.

Furthermore, it is noted that only a reasonable expectation of success is required for determinations of obviousness, rather than absolute predictability, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

Moreover, the combined teachings of Hall et al and Sengupta-Gopalan et al provide the motivation to produce the instantly claimed invention, as discussed on page 16 of the Office action of 11 March 2004.

Claims 28-29 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al. as applied to claims 19-27, 81-130, 133 and 136-138 above, and further in view of Zambryski et al. taken with Pedersen et al., as stated in the Office action of 27 September 2001 on pages 21-22.

Applicant's arguments filed on pages 10-11 of the response of 09 July 2004 have been fully considered but they are not persuasive.

Applicants urge that the art rejection over Hall et al taken with Sengupta-Gopalan et al, further in view of Zambryski et al and Pedersen et al, is improper, since the tertiary and quarternary references do not cure the deficiencies of the primary and secondary references. The Examiner maintains that the primary and secondary references taken together are not deficient, as stated above.

Claims 1-18 remain free of the prior art for the reasons presented in allowed parent application 08/105,852 corresponding to U.S. Patent 5,753,475, as stated on page 17 of the Office action of 11 March 2004.

Claims 131-132 remain free of the prior art, given the failure of the prior art to teach or suggest a method for obtaining light-induced heterologous gene expression specifically in chloroplast-containing plant tissue, as stated in allowed related application Serial No. 08/484,941 which issued as U.S. Patent 5,750,385., as stated on page 17 of the Office action of 11 March 2004.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

August 11, 2004

DAVID T. FOX
PRIMARY EXAMINER

GROUP 1638

Deeerd *20*